JUL - 6 2001

K011099

# 510(k) Summary

**Name of Sponsor:**

**DePuy Orthopaedics, Inc.**
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

**510(k) Contact:**

**Marcia J. Arentz**
Senior Regulatory Associate
Phone: (219) 371-4944
FAX: (219) 371-4987

**Trade Name:**

**Global™ Fx Porous-Coated Humeral Stem**

**Common Name:**

Shoulder prosthesis, humeral head

**Classification:**

**Class II** (special controls) per 21 CFR 888.3670 Shoulder joint metal/polymer/metal non-constrained or semi-constrained porous-coated uncemented prosthesis.

**Class II** (special controls) per 21 CFR 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.

**Device Product Code:**

Code: **87 MBF** Prosthesis, Shoulder, semi-constrained, metal/polymer, Uncemented.
Code: **87 KWS** Prosthesis, Shoulder, Semi-constrained, metal/polymer Cemented.

**Substantially Equivalent Devices:**

| | |
|---|---|
| Global Fx Shoulder System | K984541 |
| Porous Coated Global Shoulder | K943300 |

**Device Description:**

The Porous-coated Global Fx humeral stem is a modified Global Fx humeral stem. Porocoat® porous coating has been added to the proximal portion of the stem. The stem is manufactured from cobalt-chromium –molybdenum alloy conforming to ASTM F-75. The stem mates with humeral heads previously cleared as Global Advantage Head (K984541), Global Advantage CTA Heads (K000575) and the Global Advantage Eccentric Humeral Head (K992065).

**Intended use:**

The Global Fx Porous-coated humeral stem, in combination with Global shoulder humeral heads, is intended for use in total or hemi-arthroplasty.

**Indications for use:**

Total or hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;

2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).
4. Rotator cuff tear arthropathy.

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.

The Global Fx porous-coated humeral stem is intended for cemented or cementless use with fixation provided by biological tissue in-growth into the porous coating.

**Substantial equivalence:**

The Global Advantage Extended Humeral Head is substantially equivalent to the Global Fx Humeral Stem cleared in K984541. Both humeral stems have identical locking tapers, are tapered in design, come in similar sizes and are manufactured from the same materials. The only difference between the two stems is the addition of porous coating to the proximal portion of the stem.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Marcia J. Arentz
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K011099
Trade Name: Global™ Fx Porous-Coated Humeral Stem
Regulation Number: 888.3670 and 888.3660
Regulatory Class: II
Product Code: MBF and KWS
Dated: April 10, 2001
Received: April 11, 2001

Dear Ms. Arentz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):** K011099

**Device Name: Global™ Fx Porous-Coated Humeral Stem**

**Indications for Use:**

Total or hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;

2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;

3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

4. Rotator cuff tear arthropathy.

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures;

2. Avascular necrosis of the humeral head.

Porocoat® Porous-Coated Components
Porocoat porous-coated humeral stem prostheses are indicated for cemented or cementless use with fixation provided by biological tissue in-growth into the porous coating.

Cemented Components
Humeral stem and Glenoid components labeled "For cemented use only" are indicated only for use with bone cement.

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use Yes (Per 21 CFR 801.109) OR Over-The-Counter Use No

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011099